

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex. rel.
YOASH GOHIL,

Plaintiff/Relator,

vs.

SANOFI U.S. SERVICES INC., et al.

Defendants.

No. 02-cv-2964

**ORDER GRANTING PLAINTIFF'S
MOTION TO COMPEL DISCOVERY
RESPONSES**

AND NOW, on this ____ day of _____, 2018, upon consideration of Plaintiff/Relator's Motion to Compel Discovery Responses (the "Motion") and any response thereto, it is hereby **ORDERED** that the Motion is **GRANTED**;

IT IS further **ORDERED** that Defendant Aventis shall produce to Plaintiff/Relator the following within forty-five (45) days of the date of this Order:

1. All documents related to the PACT program as defined in Plaintiff's Third Request for Production, including but not limited to the PACT documents maintained by Aventis' third party vendors, any PACT database, documents regarding the whereabouts of the PACT documents or database, documents related to negotiation and termination of third party contracts, documents related to the transfer of any PACT documents to or from third party vendor and/or Aventis, and documents related to the destruction of any PACT documents from 1996-2008; and
2. All documents related to Aventis PACT reimbursement managers Danielle Scelfo, Michael Furman, Rebecca Hayes, and Loreen Brown for 1996-2008.

IT IS FURTHER **ORDERED** that Aventis is prohibited from withholding any documents or testimony from Plaintiff/Relator on the basis that the documents or testimony that relate to PACT are nonresponsive or otherwise non-discoverable.

BY THE COURT:

BLANK ROME LLP
A Pennsylvania LLP
Stephen M. Orlofsky (31633)
Nicholas C. Harbist (35210)
David C. Kistler (*pro hac vice*)
One Logan Square
130 North 18th Street
Philadelphia, PA 19103
(215) 569-5500
Orlofsky@blankrome.com

CARL D. POPLAR, P.A.
Carl D. Poplar (*Pro hac vice*)
1010 Kings Highway South
Cherry Hill, NJ 08034
(856) 216-9979
Attorneys for Plaintiff/Relator, Yoash Gohil

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA ex. rel.
YOASH GOHIL,

Plaintiff/Relator,

vs.

SANOFI U.S. SERVICES INC., et al.

Defendants.

No. 02-cv-2964

**PLAINTIFF/RELATOR'S MOTION
TO COMPEL DISCOVERY
RESPONSES**

Plaintiff/Relator Yoash Gohil moves for an Order compelling Aventis to produce certain documents and prohibiting Aventis from withholding documents and testimony from Relator on the basis that they are nonresponsive, as Aventis refuses to produce all relevant documents relating to its PACT free reimbursement services program for doctors and PACT documents maintained by Aventis' third party vendors.¹

1. Beginning in or about 1996, the Aventis PACT (Providing Access to Cancer

¹ Pursuant to this Court's procedures, Relator has not included exhibits with this motion. Upon the Court's request, Relator is prepared to provide the Court with documents substantiating the contentions and quotes herein.

Therapy) program provided free reimbursement services to doctors.² The PACT program consisted of a variety of free reimbursement services designed to induce doctors to prescribe Taxotere for off-label uses by ensuring payment and guarantying that if a claim for payment was denied, Aventis would ship free replacement drugs to offset doctors' out of pocket losses.³

2. Aventis sales representatives regularly marketed the PACT services to doctors as “value-added” services and as an “extension of” the Aventis oncology sales and marketing teams because Aventis believed that “[p]hysicians will not utilize a product unless they are assured it will be paid for.” The PACT reimbursement service relates directly to violations of the False Claims Act and the federal Anti-Kickback Statute as pled in the Third Amended Complaint (“TAC”).⁴ See TAC ¶¶ 26, 29, 45, 48, 69.

3. Discovery demonstrates Aventis' intent to induce doctors to prescribe Taxotere off-label⁵ through its PACT vendors. For example, a September 2000 email from an Aventis sales

² These services included drafting and submitting appeals for denied claim, claims management, benefit investigation, filing prior authorizations, providing payer-specific billing and coding information, payer advocacy and education, and documentation support.

³ In the typical case, the doctors would pay a distributor for Taxotere and seek reimbursement from Medicare or other insurers. If payment was denied, PACT handled the appeals. Depending on the outcome of the initial appeal, PACT would perform the second level appeal, which often required PACT staff to attend hearings on behalf of doctors.

⁴ The Anti-Kickback Act, 42 U.S.C. § 1320a-7b (the “AKA”), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any “remuneration,” to “any person to induce such person” to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* As far back as 1991, the Department of Health and Human Services warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that involve the provision of free services such as billing, nursing, or other staff services to doctors. *See, e.g.*, 56 Fed. Reg. 35952-01, 35981 (July 29, 1991); 59 Fed. Reg. 65372-01, 65376 (Dec. 19, 1994). In 2003, the HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Dep't of Health & Human Servs., 68 Fed. Reg. 23731-01, 23737 (May 5, 2003), warned if “services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician) ... the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.”

⁵ For example, an Aventis employee directed PACT analyst, “Indicate that we support her decision in prescribing Taxotere for all diagnoses and that we will assist in procuring a positive reimbursement outcome for those ones out of scope.... We also stated *we can work with FDA indications as well as off label* as we respect Dr. Klein's decision to treat for all diagnoses.” *But see* Aventis's admission only that “the PACT Program provided Reimbursement Services for Taxotere to HCPs, when such Services were requested by HCPs, and that those Services included assistance in obtaining reimbursement of claims for payment from Payors for *covered uses* of Taxotere....” (emphasis added) (Supp. Ad. No. 8, April 21, 2017).

representative forwarded to a PACT analyst memorialized a physician's comment, noting that a patient had an adverse reaction to Taxotere, but the physician would "give the product another chance as long as he was reimbursed." Because the patient did not have insurance, a replacement request was provided. This free replacement guarantee eliminated any financial risk to the doctor and provided an incentive to use Taxotere off-label. To induce continued off-label prescriptions, PACT communicated with Medicare payors directly on behalf of doctors and, at times, authored appeals for claim denials for off-label uses to ensure payments to the doctors.⁶ The Aventis documents show that many appeals related to Taxotere prescribed for off-label uses.

4. Aventis even paid third-party PACT analysts an extra \$145,000 per year to provide "dedicated" office support to obtain reimbursement for off-label uses for its highest prescribers. These analysts would "actually do all of the legwork for the account and make sure the appeals are resolved, like an office manager working for the customer would do." Thus, Aventis acknowledged that services like PACT have a significant value to doctors because these services reduce, and in some instances eliminate, the administrative costs associated with obtaining payment from insurers.

5. Aventis' Admissions regarding PACT are deficient because: (1) many are non-responsive; (2) Aventis changed its responses; and (3) many responses are inconsistent with Aventis' own documents. *See supra* n.5 Ad. No. 8. For example, Aventis admitted that it paid a:

"unit of Parexel International Corporation ('Parexel') to provide certain reimbursement-related informational assistance and support to individuals using Aventis's pharmaceutical products, through their physicians ('the PACT program') and, that Aventis made payments to Parexel in accordance with that contract, and that some of those payments during the years 1996-2004 may have come from funds initially allocated to Aventis's Oncology Marketing group."

⁶ Aventis directed a PACT analyst to "always be thinking about how they can get the claim paid" and "support the physician to the fullest extent" to "take the burden away from the office."

The documents reflect that Aventis provided far more than just mere “informational assistance and support to” patients. Indeed, Aventis paid up to \$3.5 million annually for the PACT reimbursement and appeal services provided directly to doctors for free. The documents show that the vendors that administered the PACT program included Parexel and HealthBridge and, by contract, those entities maintained documents and a database for each reimbursement case, which included data about communications with the doctors, diagnosis and tumor type, off-label prescriptions, letters of medical necessity prepared by PACT for doctors and sent to Medicare, correspondence with Medicare payors, and documentation about appeals of claims denials and billing codes as well as free replacement drugs. The documents and database were required to be maintained under the third party contracts, signed by the Aventis V.P. of Marketing, and Aventis had a duty to preserve these documents under the contracts.⁷

6. Based on discovery, it appears that sometime in 2007, the PACT services and the corresponding documents and database were subsequently transferred from HealthBridge to The Lash Group. Aventis represented that PACT was transferred and the contracts with The Lash Group began in late December 2006. Relator was unable to obtain any PACT documents or database by way of subpoenas to Parexel, HealthBridge, or the Lash Group. It is unclear if the vendor PACT documents or database still exist or were destroyed.

7. After Relator determined that Aventis’ last production of records on December 8, 2017 did not include the PACT database or any internal records maintained by Parexel or HealthBridge or records related to their transfer or whereabouts, Relator sought production of “[a]ll Documents related to any contract or agreement with Aventis and Parexel, Aventis and

⁷ Aventis transitioned from Parexel to HealthBridge in or around May 2002. The agreement between the companies, entered May 28, 2002, states that “All information, documents and raw data provided to HEALTHBRIDGE by COMPANY, are owned by COMPANY. Following completion of the services outlined in an Appendix, HEALTHBRIDGE will return COMPANY data or other materials furnished to HEALTHBRIDGE.”

HealthBridge, or Aventis and The Lash Group....” Relator also requested “[a]ll Documents related to the transfer of Documents from and/or among Parexel, HealthBridge, and The Lash Group related to the PACT program,” as well as documents related to the Aventis PACT reimbursement managers.

8. On January 29, 2018 Aventis responded by producing not a single document, relying on relevancy and proportionality objections.⁸

9. Because the contracts between Aventis and Parexel, and Aventis and HealthBridge, dictate that Aventis retain the PACT documents in the event of any transition, Aventis should have records about the PACT documents and database maintained by its vendors and when it was transferred from HealthBridge to The Lash Group sometime in 2007. Aventis was on notice by at least September 11, 2006, after this case was first unsealed, of the False Claim Act allegations, and it was under a duty to preserve all relevant documents in its possession, custody, or control, including the PACT documents and database that HealthBridge maintained at the time.

10. While Aventis produced documents related to PACT, it did not preserve and produce the electronic data or hard copy documents of the Aventis reimbursement managers who ran PACT, Danielle Scelfo, and Michael Furman, who both left Aventis in March 2007.⁹

11. The PACT database contains key evidence of off-label prescriptions by doctors, submissions of payment claims for off-label uses, the denials of such claims and appeals thereof, as well as the nature and extent of free PACT services provided to individual doctors. It is important for Relator to obtain and analyze these documents and determine the whereabouts of the

⁸ Aventis objected on the basis that the requests were outside the relevant time period, 1996-2004; it did not retain Lash to manage PACT until after this time period; and discovery was closed. However, the documents in question were created between 1996 and 2004 and maintained by Parexel and HealthBridge during this time. Aventis had access to them during this time as well as upon transfer to Lash in 2007.

⁹ Aventis only produced one of Furman’s custodial documents. Aventis also did not preserve the electronic and hard documents from Rebecca Hayes, the first PACT Reimbursement Manager, employed from 1996 to 2001.

PACT database or whether it was destroyed and, if so, upon whose instruction.

12. The parties have met and conferred, but are unable to resolve this discovery dispute.

Respectfully submitted,

s/ Stephen M. Orlofsky

STEPHEN M. ORLOFSKY (31633)

NICHOLAS C. HARBIST (35210)

BLANK ROME LLP

One Logan Square

130 North 18th Street

Philadelphia, PA 19103

(215) 569-5500

CARL D. POPLAR, P.A.

Carl D. Poplar (*Pro hac vice*)

1010 Kings Highway South

Cherry Hill, NJ 08034

(856) 216-9979

Attorneys for Plaintiff/Relator, Yoash Gohil

Dated: March 13, 2018

CERTIFICATE OF SERVICE

I, STEPHEN M. ORLOFSKY, hereby certify that on March 13, 2018, I served via ECF the foregoing Motion to Compel Discovery Responses upon the following counsel of record:

Susan Bricklin, Esquire
Assistant U. S. Attorney
United States Attorney's Office,
Eastern District of Pennsylvania
Suite 1250, 615 Chestnut Street
Philadelphia, PA 19106

Richard L. Scheff, Esquire
Montgomery, McCracken, Walker & Rhoads, LLP
123 South Broad Street
Philadelphia, PA 19109-1030

Robert J. McCully, Esq.
Shook Hardy & Bacon, LLP
2555 Grand Boulevard
Kansas City, MO 64105

s/ Stephen M. Orlofsky
STEPHEN M. ORLOFSKY